

## **REMARKS**

Claims 174-200 are pending in this Application, with claims 174, 184-187, 190, and 198-200 being independent claims.

### ***Examiner Interview Summary***

Applicants appreciate the courtesies extended by the Examiner during the personal interview conducted on August 17, 2004. During the interview, claims 186, 187, 190 and 197-200 were discussed with respect to the Bailey patent. Agreement was reached during the interview that claim 187 is allowable over the Bailey patent. Applicants discussed the possibility of amending claims 186, 190, 198 and 199 to more clearly define the scope of the invention. The Examiner suggested that claim 200 requires further consideration and that the Applicants submit the substance of their arguments in response to the Office Action. Applicants have amended the claims as discussed during the interview, but reserve the right to pursue claims of similar or broader scope in future applications.

### ***Allowable Subject Matter***

Applicants appreciate the Examiner's indication of allowable subject matter in the application.

### ***The Claims Distinctly Claim the Invention***

Claim 196 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Applicants have amended the claim as discussed during the interview to more clearly define the scope of the invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. 112, second paragraph, be withdrawn.

### ***The Claims are Patentable over the Bailey Patent***

Claims 186, 190, 192-196 and 199 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,800,179 to Bailey ("the Bailey patent").

The Bailey patent discloses a minimally invasive medical procedure simulator. The device disclosed in the Bailey patent includes a housing (Fig. 2, 1) having an opening (Fig. 2, 9) in which an implement (Fig. 2, 2) can be inserted. The Bailey patent states that to simulate a “true minimally invasive surgical instrument, the implement 2 may be moved axially (or laterally) and rotationally relative to the housing” (Col. 5, ll. 27-29). The Bailey patent, however, provides no disclosure or suggestion whatsoever of any pivotable element, particularly a pivotable anatomical site.

Independent Claim 186

Independent claim 186 recites “a first peripheral motion assembly, the first peripheral motion assembly being configured to engage a first nested instrument from the plurality of nested instruments, the first peripheral motion assembly being configured to pass a second nested instrument from the plurality of nested instruments; and a second peripheral motion assembly, the second peripheral motion assembly being configured to engage the second nested instrument after the second nested instrument has passed through the first peripheral motion assembly.”

The device disclosed in the Bailey patent has no such configuration. The Bailey patent is completely silent with respect to a first peripheral motion assembly configured to engage a first nested instrument and a second peripheral motion assembly configured to engage a second nested instrument as recited in claim 186. At most, the cited disclosure in the Bailey patent at Col. 5, lines 8-22 and 37-64 addresses the structural configuration of the Bailey device, without any mention of any peripheral motion assembly that engages a nested instrument. As discussed during the interview, the Bailey patent includes, at most, a single peripheral motion assembly. For at least these reasons, independent claim 186 is allowable over the Bailey patent.

Independent Claim 190 and its dependent claims

Independent claim 190 has been amended to include allowable subject matter from claim 174 and recites “providing a pivotable mock anatomical site pivotably coupled to the housing, the pivotable mock anatomical site being configured to receive a peripheral device.” The Bailey patent fails to disclose or suggest “a pivotable mock anatomical site pivotably coupled to the housing.” For at least this reason, independent claim 190 is allowable over the Bailey patent.

Based at least on their dependence upon independent claim 190, dependent claims 192-196 are also allowable.

*Independent Claim 199*

Independent claim 199 has been amended to include allowable subject matter from claim 174 and recites “receiving a peripheral device at a pivotable mock anatomical site, the pivotable mock anatomical site having an orifice and being pivotably coupled to a housing.” The Bailey patent fails to disclose or suggest a “pivotable mock anatomical site having an orifice and being pivotably coupled to a housing.” For at least this reason, independent claim 199 is allowable over the Bailey patent.

***The claims are patentable over the Bailey patent and the Bailey patent in view of the Tuason patent***

*The Claims are patentable over the Bailey patent alone*

Claims 187-189, 191, 197, 198 and 200 were indicated as being rejected under 35 U.S.C. 103(a) as being unpatentable over the Bailey patent.

*Independent Claims 187, 198 and 200 and dependent claims 188-189*

Beyond the heading in paragraph 7 of the Office Action, the Office Action does not address independent claims 187, 198 and 200 and dependent claims 188-189 with respect to the rejection under 35 U.S.C. 103(a) based on the Bailey patent alone. The rejection of each of these claims is addressed below with respect to the rejection based on the Bailey patent and U.S. Patent No. 5,403,191 to Tuason (“the Tuason patent”). Claims 187-189, 198 and 200 are allowable for at least the reasons set forth below.

*Dependent Claims 191 and 197*

Based at least on their dependence upon independent claim 190, which is allowable over the Bailey patent for the reasons discussed above, dependent claims 191 and 197 are also allowable.

*The Claims are patentable over the Bailey patent in view of the Tuason patent*

Claims 187-189, 198 and 200 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Bailey patent in view of the Tuason patent. The Tuason patent discloses an endoscopic surgical simulator that includes a cavity into which medical instruments are introduced through “multiple pre-established apertures” in a panel positioned above the cavity. The instruments can contact various simulated organs that are positioned within the cavity. The panel is fixedly coupled to the frame of the simulator. The simulator includes resilient foam rubber plates that cover the apertures to simulate the insertion of the various medical instruments through skin, and includes foam rubber simulated organs.

*Independent Claim 187 and its dependent claims*

As discussed during the interview, independent claim 187 is allowable over the cited references, either alone or in combination. Based at least on their dependence upon independent claim 187, dependent claims 188 and 189 are also allowable.

*Independent Claim 198*

Independent claim 198 recites “detecting via a sensor a manipulation, an insertion, and a removal of the first engaged peripheral device; and detecting via a sensor a manipulation, an insertion, and a removal of the second engaged peripheral device, the detection of the manipulation, the insertion, and the removal of the first engaged peripheral device and the detection of the manipulation, the insertion, and the removal of the second engaged peripheral device occurring substantially simultaneously and being used to simulate the exchange of medical instruments during a medical procedure.”

The simulator disclosed in the Bailey patent includes a sensor (Figs. 2, 3, item 10) that “provide[s] accurate sensing of the implement 2 relative to the housing 1.” (Col. 5, ll. 35-37). The sensor in the Bailey patent includes a force sensor (Fig. 5(a), 31), a movement sensor (Fig. 2, 17), and a penetration depth sensor (Fig. 7, 43).

Unlike the present invention as recited in claim 198, the Bailey patent fails to disclose or suggest detecting insertion and removal of the peripheral device. Likewise, the Tuason patent fails to disclose or suggest any such detection via a sensor as recited in independent claim 198.

As discussed during the interview the Bailey patent and the Tuason patent fail to disclose, either alone or in combination, “the detection of the manipulation, the insertion, and the removal of the first engaged peripheral device and the detection of the manipulation, the insertion, and the removal of the second engaged peripheral device occurring substantially simultaneously” as recited in claim 198.

Additionally, unlike claim 198, which recites the simulation of “the exchange of medical instruments during a medical procedure,” neither the Bailey patent nor the Tuason patent disclose such a detection to simulate the exchange of medical instruments during a medical procedure. In fact, the Office Action, as well as the references themselves, is completely silent with respect to such a simulation. For at least these reasons, independent claim 198 is allowable over the cited references, either alone or in combination.

#### Independent Claim 200

Claim 200 recites “providing a resiliency-providing material disposed between the orifice and the sensing assembly; and providing a hollow member extending through the resiliency-providing material, the hollow member being configured to guide the peripheral device to the sensing assembly.”

The Examiner states that the use of foam rubber simulated organs in the device of the Tuason patent “more properly simulate[s] the inserting of a peripheral into a human organ as taught by Tuason for a realistic feel when manipulating the organ objects with a peripheral during a training session.” The device disclosed in the Bailey patent combined with the foam rubber organs of the Tuason patent, however, fails to meet the claim recitations. Providing the foam rubber organs of the Tuason patent “between the orifice and the sensing assembly” of the device disclosed in the Bailey patent would eviscerate the purpose of the sensing assembly of the Bailey patent. Such a combination that destroys the intended function of the recited sensing assembly is improper. Moreover, no disclosure or suggestion exists in either of the references of “a hollow member extending through the resiliency-providing material” as recited in independent claim 200. In fact, the Office Action is silent with respect to that element of the claim. For at least these reasons, independent claims 200 is allowable over the cited references, either alone or in combination.

**CONCLUSION**

All of the stated grounds of objection and rejection have been properly traversed or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections, and that they be withdrawn. Applicants believe that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that further personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Dated: November 2, 2004

Cooley Godward LLP  
ATTN: Patent Group  
One Freedom Square  
Reston Town Center  
11951 Freedom Drive  
Reston, VA 20190-5656  
Tel: (703) 456-8000  
Fax: (703) 456-8100

Respectfully submitted,  
**COOLEY GODWARD LLP**

By:



Erik B. Milch  
Reg. No. 42,887